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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,113	03/15/2002	Juerg Lareida	000364.00124	8075
7590	02/09/2007		EXAMINER	
James J Napoli Marshall Gerstein & Borun 6300 Sears Tower 233 South Wacker Drive Chicago, IL 60606-6357			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	02/09/2007	PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/088,113	LAREIDA, JUERG
	Examiner	Art Unit
	Jennifer Kim	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 September 2006, 11/21/2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2,3,5,7,8,15 and 16 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 2,3,5,7,8, 15, 16 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

Upon reconsideration, the 1.131 Declaration filed on September 11, 2006 has been considered and is deemed to overcome the 103 rejection over Du Bois (U.S. Patent No. 6,399,601B1) in view of Ratsimamanga et al. (U.S. Patent No. 5,972,342) and further in view of Clary et al. (U.S. Patent No. 5,753,225). The Finality is withdrawn. Prosecution is reopened upon a finding of new grounds of rejection as follows:

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 5, 7, 8 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Brewer et al. (XP-000991091) of record.

Brewer et al. teach that sildenafil citrate therapy in men with Parkinson's Disease (a degenerative neuropathy) is effective in men with minimal side effects. Brewer et al. teach that the male patients with Parkinson's disease has been treated with 50 to 100mg of sildenafil citrate. (abstract).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3, 5, 7, 8, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doherty, Jr. et al. (U.S. Patent No. 6,037,346) in view of de Tejada (U.S. Patent No. 6,277,884 B1).

Doherty, Jr. et al. teach a method for treating **erectile dysfunctions** in a mammalian male individual comprising administering a phosphodiesterase inhibitor including **sildenafil citrate (VIAGRA)** or a pharmaceutically acceptable salt, ester, amide or derivative thereof within the context of an effective dosing regimen. (abstract). (column 3, lines 21-25). Doherty, Jr. et al. teach the effective daily dosage of the phosphodiesterase inhibitor in the range of approximately **0.1 to 500 mg.** (column 14, lines 15-25). This dosage range encompasses Applicant's range set forth in claim 5, 7

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and 8. Doherty, Jr. et al. teach that the erectile dysfunction have been identified as **neurogenic** associated with peripheral **neuropathy caused by diabetes**. (column 1, lines 45-56).

Doherty, Jr. et al. do not teach that the erectile dysfunction patients are "in need" of treating neuropathies.

de Tejada teaches that the sexual dysfunctions are attributable to **neuropathy**. (column 3, lines 15-20).

It would have been obvious to one of ordinary skill in the art that the patient suffering from erectile dysfunction treated by sildenafil citrate taught in Doherty Jr. et al's are in "need" of treating neuropathy because erectile dysfunction condition attributes to neuropathy as taught by de Tejada. One would have been motivated to employ sildenafil in patient suffering from erectile dysfunction that are "in need" of treating neuropathy in order to avoid possible complications result from the sexual dysfunction. There is a reasonable expectation of successfully treating erectile dysfunction patient disclosed by Doherty, Jr. et al. who are "in need" of this treatment of neuropathy because erectile dysfunction attributes to further complication of neuropathy.

None of the claims are allowed.

#### ***Response to Arguments***

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Applicant's arguments with respect to claims 2, 3, 5, 7, 8, 15 and 16 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim  
Patent Examiner  
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January 15, 2007